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720-377-0773

Typed or printed name of person signing Certificate In re U.S. Patent Application serial No. 10/562,392

Title: Anesthetic composition for topical administration comprising lidocaine,

prilocaine and tetracaine

Filing Date: December 19, 2005 Attorney Docket No. 264-011-USP

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PTO Fax Number: 571-273-8300

From: Peter B. Scull, Reg. No. 37,932

Tramsitted herewith are:

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Petition for Republication (2 pages) with two pages of exhibits.

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in re Application of:

: Fernando Bouffard Fita

Applicant Appin. No.

: 10/562.392

Filed

: December 19, 2005

Title

ANESTHETIC COMPOSITION FOR TOPICAL ADMINISTRATION

COMPRISING LIDOCAINE. PRILOCAINE AND TETRACAINE

Confirmation No: 8090

Group Art Unit: not yet assigned

Examiner: not yet assigned

PETITION FOR REPUBLICATION OF CORRECTED PATENT APPLICATION PURSUANT TO 37 C.F.R. § 1.221(b)

MAIL STOP PGPUB Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The above-referenced patent application was published on June 29, 2006 and contains a material mistake made by the U.S. Patent and Trademark Office, which is apparent from the Office records. The application contains a material mistake in the international filing date (or "PCT Filed" date) on the front page of the application. The correct international filing date (or "PCT Filed" date) is "June 1, 2004," not "July 1, 2004," as mistakenly shown on the front page of the application.

The materiality of this mistake lies in the relation of the international filing date (or "PCT Filed" date) to the priority date, whereby the errantly-published PCT Filed date of July 1, 2004, suggests that the PCT application was filed later than necessary to obtain priority, and thus presents the appearance that the PCT application did not appropriately claim priority from the earlier filing in June of 2003. This is indeed not the case because the PCT application was timely filed on June 1, 2004, and correctly claimed priority to the earlier case. Applicant also submits herewith supporting documents showing: I) the relevant page of the original filing documents clearly showing the correct

Attorney Docket No: 284-011-USP

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international PCT filling date (i.e. June 1, 2004); and II) the front page of the published application showing the incorrect international filling date (i.e. July 1, 2004).

Applicant is submitting this petition within the required two months of publication of the above-referenced application and respectfully requests republication of the above-referenced application to correct the material mistake pursuant to 37 CFR § 1.221(b). Applicant believes no fees or petitions are due with this filling. However, should any such fees or petitions be required, please consider this a request therefore and authorization to charge Deposit Account No. 50-3199 as necessary.

August 25, 2006

Respectfully submitted,

Peter B. Scull, Registration No. 37,932

Attorney for Applicant

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(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2006/0140986 A1

Jun. 29, 2006 (43) Pub. Date:

ANESTHETIC COMPOSITION FOR (54) TOPICAL ADMINISTRATION

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10/562,392 (21) Appl. No.:

PCT Filed: Jul. 1. 2004

PCT/EP04/50967 PCT No.:

Foreign Application Priority Data (30)

Jun. 19, 2003 P200301548

Publication Classification

(51) Int. CL ' (2006.01) A61K 9/00 (2006.01) A61X 31/24

(52) U.S. CL 424/400; 514/537

ABSTRACT (57)

It comprises a mixture of lidocaine, prilocaine and tetracaine, or their pharmaceutically acceptable salts. The preferred composition comprises the following components in the indicated approximate w/w percentages: 1.5% of lidocaine base; 1.5% of prilocaine base; 4% of tetracaine bese; 10% of methylpynrolidene; 2% of dimethyl sulfoxide; 0.08% of topical hyaluronidase; 1.5% of guar gum; 1% of Tween-20; 0.5% of Tween-80, and the necessary amount of water to 100%. It exhibits a a high concentration on skin, a deep aneathetic effect and a significantly more rapid onset of the anesthetic effect than comparable transdermal anesthetics.

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TRANSMITTAL LETTER TO THE UNITED STATES			ATTORNEY'S DOCKET NUMBER 264-011-USP	
DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE			PRIORITY DATE CLAIMED	
	2004/050967	1 June 2004	19 June 2003	
TITLE OF INVENTION				
Anesthetic Composition for Topical Administration Comprising Lidocalne, Prilocalne and Tetracaine APPLICANT(8) FOR DO/EO/US				
Fernando Bouffard Fita				
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:				
1. 🗹 This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.				
2. Light This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.				
3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (S), (5), (8) and (21) indicated below.				
4. 🗀	The US has been elected (Article 31).		RECEIVED	
5.	A copy of the international Application	n as filed (35 U.S.C. 371(c)(2))	CENTRAL FAX CENT	
,	a ts attached hereto (required	only if not communicated by the internation	al Вилеви).	
	b. has been communicated by	the International Bureau. (courtesy copy)	A00 2 J 2000	
	c is not required, as the application was filed in the United States Receiving Office (RO/US).			
6.	An English language translation of the	International Application as filed (35 U.S.C.	. 371(c)(Z)).	
	a is attached hereto.			
	b. has been previously submit	ted under 35 U.S.C. 154(d)(4).		
7. — Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))				
	a ere ettached hereto (requir	ed only if not communicated by the Internati	onal Sureau).	
	b have been communicated I	by the international Bureau.		
, .	c have not been made; howe	ver, the time limit for making such amendm	ents has NOT expired.	
	d have not been made and w	di not be made.		
a	An English language translation of the	emendments to the claims under PCT Artic	de 19 (35 U.S.C. 371(e)(3)).	
e. 🔽	An eath or declaration of the inventor(в) (35 U.S.C. 371(c)(4)).		
10	An English language translation of the Article 36 (35 U.S.C. 371(c)(5)).	annexes of the International Preliminary Ex	amination Report under PCT	
· Items	11 to 20 below concern document(a)	or information included:	1	
11. 🗸	An Information Disclosure Statement	inder 37 CFR 1.97 and 1.98.		
12.	An easignment document for recording	7. A separate cover sheet in compliance with	37 CFR 3.28 and 3.31 to Included	
13. 🔽	A preliminary amendment.			
14. 🔲	An Application Data Sheet under 37 C	FR 1.78.		
15.	A substitute specification:			
18, 🗸	A power of attorney and/or change of a	address letter. (as part of Declaration)		
17.	A computer-readable form of the seque	ence listing in accordance with PCT Rule 13	ter.2 and 37 CFR 1.821-1.825.	
18	A second copy of the published interns	tional Application under 35 U.S.C. 154(d)(4).	
19. 🔲	A second copy of the English language	translation of the international application u	inder 35 U.S.C. 154(d)(4).	

This collection of information is required by S7 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information; preparing, and submitting the completed form to the USPTO. Time will very depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.